

## REMARKS

Applicant initially would like to thank Examiner Melissa Ryckman for the courtesies extended Applicant's representative during the phone interview held on June 10, 2008, summarized above.

By way of summary, prior to this Amendment Claims 1-7, 10-13, 15, 16, and 48-54 were pending in this application. In the outstanding Office Action of March 17, 2008, Claims 1-7, 10-13, 15, 16 and 48-54 were rejected under 35 U.S.C. §112 as failing to comply with the enablement requirement. Claims 1-5, 7, 10, 12, 13, 15, 48, 49 and 52 were rejected under 35 U.S.C. §102(e) as anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Peavey (U.S. 2003/0225421). Claims 11, 16, 50, 51, 53 and 54 were rejected under 35 U.S.C. §103(a) as being obvious over Peavey in view of Shaw (U.S. 6,171,329). Claims 1 and 10 have been amended. Claims 55 and 56 have been added.

### **I. § 112 Claim Rejection**

In the outstanding Office Action of March 17, 2008, the Examiner rejected Claims 1-7, 10-13, 15, 16 and 48-54 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Applicant maintains that Claims 1-7, 10-13, 15, 16 and 48-54 are enabled for at least the following reasons.

First, Applicant points out that Figure 2A shows a locking element/closure device combination. The combination is not illustrated in position in a defect of a heart. The Examiner asserts that "... the locking element 228 ... crossing in a diagonal path between 206b and 210b and between 210 and 230 ... would cut into the tips of the septum primum and the septum secundum ... would not provide a use of the invention as claimed." However, this assertion is speculation on the part of the Examiner. The specification is silent on whether or not the locking element 228 would cut into the tips of the septum primum and the septum secundum. It is well known that the septa are soft tissue and can reasonably be expected to locally deflect in the presence of a locking element such as 228. Also, in one variation locking element 228 is a string, which, when implanted in a defect of a heart, can be reasonably be expected to deflect along a non-linear path between 206b and 210b and between 210 and 230. Although a portion of the locking element may appear taut in the schematic figures outside a defect of a heart, the locking element performs its function of retaining elements 206, 208 & 210 whether taut or not.

Second, whether or not the locking element 228 would cut into the tips of the septum primum and the septum secundum is likely irrelevant to the function of the locking element. If the locking element did cut into the tips then the septa would still be retained by the elements 206, 208 & 210. If the locking element did not cut into the tips but rather was deflected into a non-linear path then the septa would also be retained by the elements 206, 208 & 210.

Finally, the instant specification explains (at [0098] as filed) that “Other details regarding the locking element ... may be found in U.S. Pat. No. 5,861,003, which is hereby incorporated by reference in its entirety.” Briefly, Latson ‘003 describes use of “a superelastic wire frame pre-programmed to assume a desired shape when tension upon the wire frame is released” (see Summary of Invention). Such a wire, incorporated into the claimed device, would function as a locking element.

Accordingly, Applicant submits that the claims are enabled, and respectfully requests the Examiner to reconsider and withdraw the enablement rejection of Claims 1-7, 10-13, 15, 16 and 48-54.

## **II. § 102(e) and §103(a) Claim Rejections**

In the outstanding Office Action of March 17, 2008, Claims 1-5, 7, 10, 12, 13, 15, 48, 49 and 52 were rejected under 35 U.S.C. §102(e) as anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Peavey (U.S. 2003/0225421). As discussed during the Interview, Claims 1 and 10 have been amended to overcome this rejection, and the Examiner appeared to agree that the rejection under 35 U.S.C. §102(e) as anticipated by, or in the alternative, under 35 U.S.C. §103(a) should be withdrawn. Claim 1 now recites, in part, “locking the position of the proximal segment, the intermediate segment and the distal segment of the closure device after deployment with a locking element that is separate from the proximal segment, intermediate segment and the distal segment.” The separate locking element embodiment recited in Claim 1 is supported in the specification and the figures with the separate reference number indicated as locking element 228. Claim 10 now recites, in part, “locking the closure device in its clip configuration after deployment with a locking element to increase the clamping force of the closure device on the septa of the patent foramen ovale.” This amendment to Claim 10 is supported by the specification at [0098] as filed. Applicant submits that Claims 1

and 10 are neither anticipated nor rendered obvious by Peavey, and therefore, Claims 1 and 10 are allowable.

Dependent Claims 2-5, 7, 11, 12, 13, 15, 48, 49 and 52 depend from amended Claims 1 and 10 and further define the invention of Claims 1 and 10. Applicant thus submits that Claims 2-5, 7, 11, 12, 13, 15, 48, 49 and 52 are patentable over Peavey for the same reasons as above, and because of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of 1-5, 7, 10, 12, 13, 15, 48, 49 and 52 based on Peavey.

### **III. §103(a) Claim Rejections**

In the outstanding Office Action of March 17, 2008, Claims 11, 16, 50, 51, 53 and 54 were rejected under 35 U.S.C. §103(a) as being unpatentable over Peavey in view of Shaw (U.S. 6,171,329). Shaw discloses a guiding mandrel 42 that temporarily engages eyelets 44, 46, 48 in a helical closure device. The guiding mandrel 42 is withdrawn from the helical closure device and the body of the patient upon deployment of the helical closure device. Shaw's guiding mandrel does not address the deficiencies of Peavey described above. Dependent Claims 11, 16, 50, 51, 53 and 54 depend from amended Claims 1 and 10 and Claims 11, 16, 50, 51, 53 and 54 further define the invention of Claims 1 and 10. For at least the reasons set forth above with respect to Claims 1 and 10, Applicant respectfully submit that Claims 11, 16, 50, 51, 53 and 54 are patentable over Peavey in view of Shaw. Claims 11, 16, 50, 51, 53 and 54 are also patentable over Peavey in view of Shaw in view of the additional limitations recited in each respective claim. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 11, 16, 50, 51, 53 and 54 based on Peavey in view of Shaw.

### **IV. New Claims**

New dependent Claims 55 and 56 have been added. All of these new dependent claims are directed to a locking element that remains within the patent foramen ovale upon deployment. For the reasons discussed above, none of the references cited by the Examiner teach or suggest methods as claimed. Accordingly, Applicant submits that these new claims are allowable over the cited art.

**V. No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

**VI. Co-Pending Applications of Assignee**

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed	Matter Reference
11/584828	TISSUE OPENING OCCLUDER	10/23/2006	EV3.062DV1
11/607237	TISSUE OPENING OCCLUDER	11/30/2006	EV3.062DV2
11/927448	TISSUE OPENING OCCLUDER	10/29/2007	EV3.062C1
10/419412	SEPTAL DEFECT OCCLUDER	4/21/2003	EV3.058CPC1
10/227773	DEFECT OCCLUDER RELEASE ASSEMBLY AND METHOD	8/26/2002	EV3.059C1
12/110186	RETRIEVABLE SEPTAL DEFECT CLOSURE DEVICE	4/25/2008	EV3.067C1C1
10/972635	PATENT FORAMEN OVALE CLOSURE SYSTEM	10/25/2004	EV3.079A
10/783783	DEVICES AND METHODS FOR CLOSING A PATENT FORAMEN OVALE WITH A COIL-SHAPED CLOSURE DEVICE	2/20/2004	MVMDINC.060A
10/841880	DEVICES AND METHODS FOR CLOSING A PATENT FORAMEN OVALE USING A COUNTERTRACTION ELEMENT	5/7/2004	MVMDINC.068A

Appl. No. : 10/771,845  
Filed : February 4, 2004

## **VII. Conclusion**

Applicant respectfully submits that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein.

Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity. However, if the Examiner has any questions or concerns, the Examiner is invited to telephone Applicant's attorney of record so that extended prosecution of this application may be avoided.

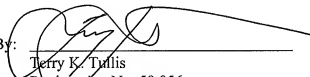
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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